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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,534	01/22/2002	Abderrahim Bennis	01198	7735

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EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/03/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,534

Applicant(s)

BENNIS ET AL.

Examiner

Clinton Ostrup

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1-10 are pending in this application.

Priority

Priority to PCT/FR00/01365, filed May 19, 2000 and France Application Number 99 06325, filed May 19, 1999 has been acknowledged.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on May 19, 1999. It is noted, however, that applicant has not filed a copy of a certified copy of the French application as required by PCT Rule 17.2(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 4-5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Helden et al., 3,607,271. Claims 1-10 claims a system which "is capable of providing a buffering effect between pH 3 and pH 7" the claim does not positively recite that such a pH range is provided. Moreover, claim 1 is directed to a composition for oral administration of phloroglucinol, not a composition comprising phloroglucinol. Although the claim describes the composition as being capable of providing a pH of between pH 3 and pH 7 it does not positively recite that the composition does provide a pH between 3-7.

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The Helden reference teaches an aqueous phloroglucinol solution buffered to a pH between 4 and 8 and containing 1-10 percent by volume of a water-miscible organic solvent. In Example V the reference teaches a composition comprising phloroglucinol, citric acid, water, and a base, therefore meeting the limitations of instant claims 3, 4, 5, and 10. The reference specifically teaches the pH of the composition as being pH 6, thus meeting the limitations of instant claims 1-2 and 10.

Thus, Helden et al anticipate claims 1-3, 4-5, and 10.

W/d
Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotz & Treichel, Chemistry & Chemical Reactivity, Third Edition, pp.860-861. Claim 1 is drawn to a composition for oral administration of phloroglucinol, not a composition comprising phloroglucinol. In fact, the only positive recited claim characteristics is that the composition be in a liquid or solid state and be capable of providing a buffer effect between pH 3 and pH 7, not that it does provide said buffering effect. Thus, instant claims 1-3 are anticipated by the commonly used buffering system acetic acid, which is a useful buffering system at a pH range of 3.7-5.8. See: Table 18.2 on page 860. Moreover, acetic acid buffered solutions comprising a acetic acid/sodium acetate buffer are clearly taught on page 861, along with methods for determining the specific pH of said buffer solution when hydrochloric acid is added.

Thus, giving claims 1-3 a broad interpretation, they are clearly taught by Kotz & Treichel.

W/d
Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayer Bitterfeld GmbH, Almany, Alka-Seltzer.

As discussed above, there is no requirement that phloroglucinol be present in the composition of claims 1-9 and Alka-Seltzer teaches a composition comprising citric acid, sodium bicarbonate and is in the form of an effervescent tablet. The reference teaches that Alka-Seltzer keeps gastric pH between 5-7, thus meeting the limitations of claims 1-9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Although claims 1-9 have been anticipated by the references above, in the interests of compact prosecution, the examiner is making an obviousness-type rejection in anticipation of applicant adding phloroglucinol to claims 1-10.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafon, UK 904,955 taken with Blonde, UK 1,227,744 and further in view of Bayer Bitterfeld GmbH, Almany, Alka-Seltzer.

Lafon teaches pharmaceutical compositions containing phloroglucinol, wherein said compositions are made in a Tyrode solution. A Tyrode solution contains sodium chloride, potassium chloride, crystalline calcium chloride, hydrated magnesium chloride, sodium bicarbonate, sodium phosphate, glucose and water. The primary reference teaches phloroglucinol in the form of cachets, capsules, powders, and tablets, which all give equally good results when administered orally. The reference teaches that other substances may be administered with the phloroglucinol such as solid or liquid carriers or a dispersants and specifically teach examples of cachets, capsules, sugared tablets, and injectable ampoules in Examples 1-6 on page 3.

Blonde teaches compositions comprising phloroglucinol, sodium saccharinate, and other substances such as acetyl-salicylic acid. The secondary reference teaches that the compositions can be in the form of lumps containing medicaments and said lumps are used because they allow the drugs to be instantly dissolved in water, allowing the drugs to be delivered orally in solutions.

Although the primary and secondary references both teaches solid and liquid forms of compositions comprising phloroglucinol for oral administration, the references are silent with respect to the pH of the compositions and lack the acids of instant claim 4-5 and 9 as well as the effervescent tablet of instant claims 7-9.

Alka-Seltzer comprises citric acid, sodium bicarbonate and is in the form of an effervescent tablet.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the phloroglucinol containing compositions of the

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primary and secondary references, by adding phloroglucinol to the effervescent tablet as taught by Alka-Seltzer, because of the reasonable expectation of obtaining an effervescent tablet capable of delivering an oral dosage form of the antispasmodic active ingredient in a tablet form which is quickly dissolvable in water.

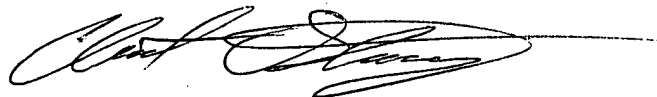
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614



February 25, 2003

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1600

